K100668

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

DEC 8 2010

Device Name
Proprietary Device Name: NeMa-st

Establishment Name and Registration Number of Submitter
Name: Nevomatrix Ltd.
Corresponding Official: Dan Laor
Sireni 6, Haifa 32972, Israel
TEL: 972-4-8246632

Device Classification

Product Code:	GZJ
CFR section:	882.5890
Panel Identification:	Neurology
Device Description:	Stimulator, nerve, transcutaneous, for pain relief
Classification:	Class II Product

Reason for 510(k) Submission
Traditional 510(k) Submission

Identification of Legally Marketed Predicate Devices
K062354 Vectra Genisys
K060517 Pointer Excel

Device Description
The NeMa-st is a pain relief treatment console, which includes Screen, Mouse, Keyboard, Processor, embedded Software, Power Supplies and the stimulator circuitry and probes.

Intended use and indications for Use
NeMa-st is intended for Transcutaneous Electrical Nerve Stimulation (TENS) for back pain relief. NeMa-st is indicated for the relief and management of symptomatic chronic or intractable back pain and/or post-surgical back pain and/or post trauma back pain.

Safety & Effectiveness
The device has been designed, verified and validated complying to 21CFR 820.30 regulations. The device has been certified to IEC 60601-1, IEC 60601-1-2 & IEC 606012- 10 Safety standards. This certification and the results of performance bench and validation testing demonstrate the device safety and effectiveness.

Substantial Equivalency
It is Nervomatrix opinion that the NeMa-st is substantially equivalent in terms of safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Nervomatrix Ltd.
c/o Mr. Dan Laor
Sireni 6,
Haifa 32972
Israel

DEC - 8 2010

Re: K100668
Trade/Device Name: NeMa-st, model v1.0.2
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: unclassified
Product Code: GZJ
Dated: November 14, 2010
Received: November 18, 2010

Dear Mr. Laor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100668

Device Name: Nema -st model v1.0.2

Indications For Use:
NeMa-st is intended for Transcutaneous Electrical Nerve Stimulation (TENS) for back pain relief. NeMa-st is indicated for the relief and management of symptomatic chronic or intractable back pain and/or post-surgical back pain and/or post trauma back pain.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K100668